REMARKS

Claims 1, 6 and 7 are currently pending. No claims have been amended. No new claims have been added.

Claims 1, 6 and 7 have been rejected under 35 USC § 103(a) over Gast '405, in view of Morita, Merck, Jain et al., Sebhatu et al, Rialkaret al, and Bouckton et al.

As the Examiner acknowledges, Gast teaches a hormonal product wherein the excipient is in crystalline or non-crystalline form. There is no teaching or suggestion in Gast of such a product wherein the steroid hormone is in non-crystalline form, as required by the claimed invention. Morita also relates only to the lactose excipient, noting that lactose has been widely used in pharmaceutical preparations and that several grades are available, including non-crystalline lactose. Morita says nothing about a hormonal product wherein a steroid hormone is in non-crystalline form. Jain merely states that a hydrophobic drug may stabilized in the presence of hydrous and anhydrous lactose. Sebhatu et al, Rialkaret al, and Bouckton et al likewise relate only to the use of lactose in pharmaceutical preparations. As to Merck, the Examiner ascribes to this reference the teaching that estrone is in non-crystalline form based on the statement in Merck that estrone can be crystalline. Even assuming that this is true, the reference still fails to teach or suggest a hormonal product which includes the steroid hormone norgestimate, wherein norgestimate is in non-crystalline form and is stabilized in this form by lactose.

The criticality of the norgestimate being in non-crystalline form is clearly set forth in the specification. Applicants direct the Examiner to page 6, lines 15-23 of the specification wherein it is noted that steroid hormones can exist in various solid state forms and that the particular solid state form may significantly affect properties such as dissolution rate and physical/chemical stability. It is further noted in that section of the specification that the higher energy, non-crystalline solid-state form will exhibit an increase in dissolution rate over the more stable, lower energy crystalline form. At page 7, line 30 to page 8, line 2, applicants point out that in the manufacture of steroid hormone products it would be highly desirable to increase the dissolution rate of the hormone while at the same time either improving or at least not reducing the physical/chemical stability of the hormone.

These objectives are achieved by the claimed invention, as shown by the data set forth in Tables 1-4. In particular, the data in Table 1 demonstrate the difference in dissolution rates for non-crystalline norgestimate as compared to the lower-energy

crystalline form. Note that the dissolution rate for amorphous norgestimate at 60 minutes is about the same as the lower energy crystalline form at 120 minutes and that the dissolution rate for the amorphous form at 120 minutes is significantly higher than the rate for the crystalline form at 140 minutes. The data in Tables 2 and 3 illustrates the effect on dissolution rate as norgestimate begins to re-crystallize from the higher energy amorphous form. As shown by these data, the dissolution rate of norgestimate decreases as the steroid converts to the lower energy crystalline form. The data in Table 4 show that the dissolution properties of norgestimate are not only dependent on storage conditions, but also on the mixing energetics imparted during the manufacturing process. Note that as energy is imparted over time and higher levels of amorphous norgestimate are present, the dissolution characteristics improve even when storage is unprotected under accelerated conditions.

As stated in the specification at page 13, lines 11-22, taken together the data from these studies demonstrate that when a mixture of an excipient and a steroid active ingredient is subjected to sufficient mechanical energy, the excipient and the steroid active ingredient form a less crystalline, more highly energetic composition. Furthermore, under appropriate mixing conditions, the lactose component stabilizes the steroid in a highly energetic, substantially non-crystalline state, thus preventing recrystallization of the steroid. The highly energetic, non-crystalline steroid active ingredient dissolves more readily and is better able to maintain desirable dissolution characteristics under a variety of conditions of ambient humidity and ambient temperature.

In view of the foregoing, applicants submit that the specification clearly sets forth the criticality of the non-crystalline form of norgestimate with respect to both the dissolution rate and stability. Accordingly, applicants believe that the claimed invention patentably distinguishes over the combination of references cited by the Examiner, since these references fail to teach such criticality. Accordingly, applicants request that the rejection issued under section 103 be withdrawn.

Applicants request that a Notice of Allowance be issued in this case at the earliest possible date.

Applicants do not believe that any fees are required in connection with the filing of this Response. Should any fees be required, please charge Deposit Account No. 10-0750/ORT1548/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed

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